

10/582015

AP20 Rec'd PCT/PTO 07 JUN 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Yoshihisa SHIRASAKI et al. : **Mail Stop: PCT**
Serial No. NEW : Attorney Docket No. 2006_0638A
Filed June 7, 2006 :

ALPHA-KETOAMIDE DERIVATIVE, AND
PRODUCTION METHOD AND USE THEREOF
[Corresponding to PCT/JP2004/018692
Filed December 8, 2004]

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application
PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No.
_____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the
above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

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3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☒ A foreign patent office search report citing one or more of the references is enclosed along with the Written Opinion.

Respectfully submitted,

Yoshihisa SHIRASAKI et al.

By Warren M. Cheek, Jr.
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/dlk
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
June 7, 2006

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FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

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ATTY DOCKET NO.
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APPLICANT
Yoshihisa SHIRASAKI et al.FILING DATE
June 7, 2006

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,541,290	7/1996	Harbeson et al.			
	AB	5,650,508	7/1997	Powers			
	AC	6,150,378	11/2000	Chatterjee et al.			
	AD	5,763,576	6/1998	Powers			
	AE	5,610,297	3/1997	Powers			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AF	98/50065	11/1998	WO			Abstract
	AG	94/00095	1/9994	WO			
	AH	92/12140	7/1992	WO			
	AI	02/078670	10/2002	WO			
	AJ						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	S. L. Harbeson et al., "Stereospecific Synthesis of Peptidyl α -Keto Amides as Inhibitors of Calpain", J. Med. Chem., Vol. 37, No. 18, pp. 2918-2929, 1994.
	AL	E. Caba et al., "Peptideyl α -Keto Amide Inhibitor of Calpain Blocks Excitotoxic Damage without Affecting Signal Transduction Events", Journal of Neuroscience Research, Vol. 67, No. 6, pp. 787-794, 2002.
	AM	K. A. Josef et al., "Potent Peptide α -Ketohydroxamate Inhibitors of Recombinant Human Calpain I", Bioorganic & Medicinal Chemistry Letters, Vol. 11, No. 19, pp. 2615-2617, 2001.
	AN	I. O. Donkor et al., "Significance of Hydrogen Bonding at the S ₁ ' Subsite of Calpain I", Bioorganic & Medicinal Chemistry Letters, Vol. 11, No. 13, pp. 1753-1755, 2001.
	AO	R. L. DeBiasi et al., "Calpain Inhibition Protects against Virus-Induced Apoptotic Myocardial Injury", Journal of Virology, Vol. 75, No. 1, pp. 351-361, January 2001.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	BA	5,444,042	8/1995	Bartus et al.			
	BB	6,686,335	2/2004	Mallamo et al.			
	BC						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	BD						
	BE						
	BF						
	BG						
	BH						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	BI	I. O. Donkor et al., "Synthesis and Calpain Inhibitory Activity of α -Ketoamides with 2,3-Methanoleucine Stereoisomers at the P ₂ Position", Bioorganic & Medicinal Chemistry Letters, Vol. 10, No. 22, pp. 2497-2500, 2000.
	BJ	J. F. Harriman et al., "Efficacy of Novel Calpain Inhibitors in Preventing Renal Cell Death", The Journal of Pharmacology and Experimental Therapeutics, Vol. 294, No. 3, pp. 1083-1087, 2000.
	BK	K. E. Saatman et al., "Behavioral Efficacy of Posttraumatic Calpain Inhibition is not Accompanied by Reduced Spectrin Proteolysis, Cortical Lesion, or Apoptosis", Journal of Cerebral Blood Flow and Metabolism, Vol. 20, No. 1, pp. 66-73, 2000.
	BL	T. James et al., "New Inhibitors of Calpain Prevent Degradation of Cytoskeletal and Myelin Proteins in Spinal Cord <i>In Vitro</i> ", Journal of Neuroscience Research, Vol. 51, No. 2, pp. 218-222, 1998.
	BM	Z. Li et al., "Novel Peptidyl α -Keto Amide Inhibitors of Calpains and Other Cysteine Proteases", Journal of Medicinal Chemistry, Vol. 39, No. 20, pp. 4089-4098, 1996.
	BN	K. E. Saatman et al., "Calpain Inhibitor AK295 Attenuates Motor and Cognitive Deficits Following Experimental Brain Injury in the Rat", Proceedings of the National Academy of Sciences of the United States of America, Vol. 93, No. 8, pp. 3428-3433, April 1996.

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	CA						
	CB						
	CC						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	CD						
	CE						
	CF						
	CG						
	CH						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	CI	R. T. Bartus et al., "Calpain Inhibitor AK295 Protects Neurons from Focal Brain Ischemia", Stroke, Vol. 25, No. 11, pp. 2265-2270, November 1994.
	CJ	C. Wu et al., "High-Performance Liquid Chromatographic Reversed-Phase and Normal-Phase Separation of Diastereomeric α -ketoamide Calpain Inhibitors", Journal of Chromatography A, Vol. 684, No. 2, pp. 243-249, 1994.
	CK	I. O. Donkor et al., "Design, Synthesis, Molecular Modeling Studies, and Calpain Inhibitory Activity of Novel α -Ketoamides Incorporating Polar Residues at the P ₁ '-Position", Journal of Medicinal Chemistry, Vol. 47, No. 1, pp. 72-79, 2004.
	CL	P. Mathur et al., "Cellular Events Preceding Acetaminophen Cataractogenesis Studied by Confocal Fluorescence Microscopy", Journal of Ocular Pharmacology and Therapeutics, Vol. 19, No. 5, pp. 483-492, 2003.
	CM	
	CN	

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